

Article - Health - General

[\[Previous\]](#)[\[Next\]](#)

§21–249.

(a) (1) For the purpose of enforcing this subtitle and after presentation of appropriate credentials to the owner, operator, or agent in charge, the Secretary or a representative of the Secretary may enter and inspect at any reasonable time:

(i) Any factory, warehouse, or other establishment in which any food, drug, device, or cosmetic is manufactured, processed, packed, or held for a commercial purpose; and

(ii) Any vehicle used to transport or hold any food, drug, device, or cosmetic for a commercial purpose.

(2) An inspection carried out under this section may include an inspection of the establishment or vehicle itself and of any pertinent equipment, labeling, and finished and unfinished products.

(3) An inspection carried out under this section shall be completed with reasonable promptness.

(b) (1) As to any factory, warehouse, consulting laboratory, or other establishment in which any prescription drug is manufactured, processed, packed, or held, an extended inspection under this section shall include everything in the establishment that may have a bearing on whether the establishment has violated a provision of this subtitle regarding prescription drugs, including the records, processes, controls, and facilities.

(2) The authority under this subsection to conduct extended inspections of the records of an establishment that relate to prescription drugs does not include the authority to inspect records of the establishment that relate to:

(i) Financial information;

(ii) Sale information, other than shipment information;

(iii) Pricing information;

(iv) Personnel information, other than information as to the qualifications of technical and professional personnel who perform functions subject to this subtitle; or

(v) Research information, other than information that:

1. Relates to a new drug or an antibiotic drug and is subject to requirements for reporting and inspection that are imposed by rules and regulations adopted under § 355(i) or (k) or § 357(d) or (g) of the federal act; or

2. Relates to any other drug and would be subject to reporting or inspection under rules and regulations adopted under § 355(k) of the federal act.

(3) Authority to conduct extended inspections under this subsection does not apply to:

(i) Any pharmacy that complies with the laws of this State that regulate practicing pharmacy or medicine and that does not, through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process any drug for sale, other than in the regular course of its business of dispensing or selling drugs at retail;

(ii) Any health practitioner who is authorized by law to prescribe or administer drugs and who manufactures, prepares, propagates, compounds, or processes a drug solely for use in the course of the practitioner's professional practice;

(iii) Any person who manufactures, prepares, propagates, compounds, or processes any drug for use only in research, teaching, or chemical analysis, and not for sale; or

(iv) Any other class of person that the Secretary by rule or regulation exempts from the application of this subsection after a finding that, for that class of person, an inspection in accordance with this subsection is not necessary for the protection of the public health.

(c) (1) During any inspection under this section, the Secretary may obtain a sample of any item that is subject to the inspection.

(2) When obtaining a sample from an establishment under this subsection, the Secretary shall give the owner, operator, or agent in charge a receipt that describes the sample obtained.

(d) On completing an inspection under this section and before leaving the establishment, the Secretary or representative of the Secretary shall:

(1) Make a written report that sets forth any condition or practice that was observed during the inspection and that indicates that any food, drug, device, or cosmetic in the establishment:

- (i) Contains any filthy, putrid, or decomposed substance; or
- (ii) Has been prepared, packed, or held under unsanitary conditions by which it:
 - 1. May have become contaminated with filth; or
 - 2. Otherwise may have been rendered injurious to health; and

(2) Give the owner, operator, or agent in charge of the establishment a copy of the report.

[\[Previous\]](#)[\[Next\]](#)